

Remarks

With this response, Claims 1-41 are pending, of which claims 16-18, 21-23, and 38-40 are withdrawn from consideration as being drawn to non-elected species. By way of the present amendment, Claims 1, 5-7, 10, 24, and 28-30 have been amended without prejudice or disclaimer of the underlying subject matter. No new matter enters by way of these amendments or additions. Support for these amendments can be found throughout the claims and specification as originally filed. For instance, see the discussion at paragraph [0027] of the specification.

I. Formal Matters

The Examiner notes that the specification must be amended to make specific reference to any earlier patents of patent applications which the present applications makes a claim of priority. The specification has been so amended. As such, acknowledgment of the priority claim under 35 U.S.C. § 119(e) is respectfully requested.

II. Rejections under 35 U.S.C. § 112, second paragraph

Claims 5-7, 14, 28-30 and 36 stand rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Withdrawal of these rejections is respectfully requested for at least the reasons which follow.

Claim 5 is allegedly indefinite due to the recitation of the phrase “about 1 μ g-30 μ g to about 1 mg.” Claims 6, 7, and 28-30 are allegedly similarly indefinite. Applicants have amended claims 5-7 and 28-30 to delete reference to “ - 30 μ g.” However, such amendments do not narrow the scope of the claims in any regard. Accordingly, it is submitted that the claims comply with 35 U.S.C. § 112, second paragraph, and withdrawal of this rejections is respectfully requested.

Claims 14 and 36 are allegedly indefinite due to the recitation of the phrase “analog or derivative.” This rejection is respectfully traversed. It is submitted that one of ordinary skill in the art would clearly understand the metes and bounds of the terms

“analog” and “derivative” in the context of exendin peptides. Further, contrary to the assertion of the Examiner, the specification does provide guidance as to the scope and meaning of such claim terms. For example, see the discussion on pages 11 and 12 of the specification, which describes such terms and including, at a minimum, variants of an exendin molecule. As such, withdrawal of this rejection is respectfully requested.

III. Rejection under 35 U.S.C. §112, first paragraph

Claims 1-15, 24-37 and 41 stand rejected as allegedly being non-enabled. In support of this rejection, the Examiner acknowledges enablement for a method for lowering or reducing triglyceride levels, but alleges that the specification “does not reasonably provide enablement for claims to a method for *modulating* triglyceride levels.” *Office Action mailed April 10, 2003, Paper No. 25*, at page 4 (emphasis in original). This rejection is respectfully traversed. However, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer to refer to the lowering of triglyceride levels. As such, withdrawal of this rejection is respectfully requested.

IV. Rejection under 35 U.S.C. § 102(b)

Claims 1, 3, 5, 6, 9-14, 19, 20, 24, 26, 28, 29, 32-36 and 41 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Beeley et al., WO 98/30231 (hereinafter, “Beeley”), as evidenced by Beers et al., the Merck Manual (hereinafter, “Beers”). This rejection is respectfully traversed, and to the extent that it applies to the amended claims, reconsideration is requested for at least the reasons that follow.

The Examiner acknowledges that “Beeley does not specifically mention the term ‘triglyceride’,” but contends that “Beeley’s method for lowering plasma lipids would inherently lower the triglyceride levels.” *Office Action mailed April 10, 2003, Paper No. 25*, at page 6. Applicants respectfully disagree.

Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744,

747 (Fed. Cir. 1987). However, a prior art reference may anticipate a claim without expressly disclosing a feature of the claimed invention if that missing feature is necessarily present, or inherent, in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). In this regard, inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure if “the result is a necessary consequence of what was deliberately intended.” *Mehl/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999), *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002);

The presently amended claims relate to the lowering of triglyceride levels. The claimed methods include identifying a patient with elevated triglyceride levels (or elevated postprandial triglyceride levels), followed by the administration of a therapeutically effective amount of an exendin or an exendin agonist.

Although Beeley does discuss the use of exendins in the lowering of “plasma lipids” generally, the reference does not discuss the use of exendins in the reduction of triglycerides specifically (triglycerides are a subset of total plasma lipids, which include, *e.g.*, LDL, HDL, VLDL, and cholesterol). Moreover, the discussions of the lowering of plasma lipids are in the context of a reduction in food intake. As such, whatever else Beeley does disclose, the reference does not recognize the ability of exendins to specifically lower triglycerides as an independent mode of action. The “necessary consequence of what was deliberately intended” in Beeley relates to the reduction of food intake. In this regard, Beeley does not teach or suggest the identification of a subject with elevated triglyceride levels, followed by the administration of a therapeutically effective amount of an exendin or exendin agonist.

For at least the foregoing reasons, it is respectfully submitted that the claims are novel over Beeley since, at a minimum, the reference does not disclose or suggest the aforementioned limitations. As such, withdrawal of this rejection is respectfully requested.

V. Rejection under 35 U.S.C. § 103(a)

Claims 2, 4, 7, 8, 25, 27, 20 and 31 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Beeley. This rejection is respectfully traversed, and to the extent that it applies to the amended claims, reconsideration is requested for at least the reasons that follow.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on applicant's disclosure. *See* M.P.E.P. §§2143.01 and 2143.03.

As discussed above, Beeley does not discuss the use of exendins in the reduction of triglycerides specifically, and the discussions of the lowering of plasma lipids are in the context of a reduction in food intake. As such, Beeley does not teach or suggest the identification of a subject with elevated triglyceride levels, followed by the administration of a therapeutically effective amount of an exendin or exendin agonist.

Claims 15 and 37 also stand rejected under 35 U.S.C. §103(a) as alleged being unpatentable over Beeley in view of Wagle et al. US 6,326,396 B1 (hereinafter, "Wagle"). This rejection is respectfully traversed. Whatever else Wagle does disclose, it too does not recognize the ability of exendins to lower plasma triglycerides as an independent mode of action. As such, Wagle does not remedy the deficiencies of Beeley in this regard.

In sum, it is submitted that the prior art of record does not disclose or suggest the ability of exendins to specifically lower triglyceride levels, or suggest the identification of a subject with elevated triglyceride levels. As such, the cited references do not render the present claims obvious. For at least the foregoing reasons, it is respectfully submitted that all of the pending claims are non-obvious over the prior art of record, since at a minimum they do not include or suggest the aforementioned limitations. As such, withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-6111 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Milan M. Vinnola".

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Date: September 10, 2003

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